

SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, D.C. 20549



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FORM 6-K

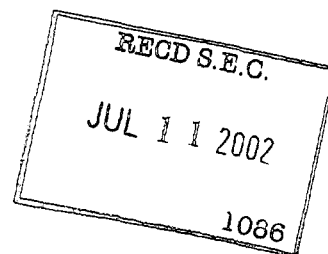
REPORT OF FOREIGN PRIVATE ISSUER  
PURSUANT TO RULE 13a-16 OR 15d-16 OF  
THE SECURITIES EXCHANGE ACT OF 1934

For the month of July, 2002.

*PE 7-1-02*  
\_\_\_\_\_  
Serono S.A.  
(Registrant's Name)

15 bis, Chemin des Mines  
Case Postale 54  
CH-1211 Geneva 20  
Switzerland  
\_\_\_\_\_  
(Address of Principal Executive Offices)

\_\_\_\_\_  
1-15096  
(Commission File No.)



PROCESSED

*P* JUL 17 2002  
THOMSON  
FINANCIAL

(Indicate by check mark whether the registrant files or will file annual reports under cover of Form 20-F or Form 40-F.)

Form 20-F ☒ Form 40-F ☐

(Indicate by check mark whether the registrant by furnishing the information contained in this form is also thereby furnishing the information to the Commission pursuant to Rule 12g3-2(b) under the Securities Exchange Act of 1934.)

Yes ☐ No ☒

(If "Yes" is marked, indicate below the file number assigned to the registrant in connection with Rule 12g3-2(b): 82-\_\_\_\_)

*W. May*



## **Media Release**

### **FOR IMMEDIATE RELEASE**

#### **SERONO AND PFIZER TO CO-PROMOTE MULTIPLE SCLEROSIS TREATMENT REBIF® IN THE UNITED STATES**

**Geneva, Switzerland, Rockland, MA, USA, and New York, USA,  
July 11, 2002** - Serono S.A. (virt-x: SEO and NYSE: SRA) and Pfizer Inc. (NYSE: PFE) today announced an agreement to co-promote Serono's multiple sclerosis (MS) treatment Rebif® (interferon beta 1-a) in the United States.

Rebif® has been shown to decrease the frequency of clinical exacerbations and delay the accumulation of physical disability associated with relapsing forms of MS. Rebif® is approved for use in the United States and Europe and is registered for use in more than 70 countries worldwide.

"We are delighted to work with Pfizer as our marketing partner for Rebif® in the U.S.," said Ernesto Bertarelli, Chief Executive Officer of Serono. "The combined strengths of our companies will enable us to build on the strong momentum Rebif® has achieved since its launch, and to accelerate the market penetration of Rebif® in the U.S."

Under the terms of the agreement, Pfizer will pay Serono an up-front fee of \$200 million, will share all commercialization and development costs in the U.S., and will receive a payment based on Rebif® sales in the United States. Serono will record all sales and continue to distribute the product in the U.S. The dedicated sales forces of the two companies will provide Rebif® with significantly greater reach than MS competitors in the U.S. The product will continue to be sold under the Rebif® brand name. Serono will continue to be sole marketer for Rebif® in the rest of the world.

"As the leading treatment for MS outside the U.S., Rebif® fits well with our goal to meet patient needs in significant diseases," said Pfizer Chairman and Chief Executive Hank McKinnell. "Rebif® also complements our broad portfolio of products that treat neurological disorders and further supports Pfizer's leading position in neurology."

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## ***About Multiple Sclerosis***

Multiple sclerosis is a chronic, inflammatory condition of the nervous system and is the most common non-traumatic neurological disease in young adults. MS affects approximately 350,000 Americans. While symptoms can vary, the most common symptoms of MS include blurred vision, numbness or tingling in the limbs and problems with strength and coordination. The relapsing forms of the disease are the most common forms of MS.

## ***FDA approval of Rebif®***

The U.S. Food and Drug Administration approved Rebif® on March 07, 2002 under the terms of the Orphan Drug Act (ODA) for the treatment of patients with relapsing forms of MS. Until this approval by the FDA, Rebif® could not be marketed in the U.S. due to the Orphan Drug status of another interferon beta-1a product, Avonex®, whose exclusivity under the ODA was granted in 1996 and will not expire until May 2003. Rebif® was able to overcome this Orphan Drug exclusivity and gain marketing approval under the terms of the ODA by demonstrating clinical superiority over Avonex® at 24 weeks in the EVIDENCE head-to-head study.<sup>1</sup> This is the first time in the history of the ODA that a new product has been approved on the basis that it is more effective than the existing approved orphan drug. The ODA, approved in 1983, provides drug makers with commercial incentives to encourage the development of treatments for patients with rare and debilitating diseases.

## ***About Rebif®***

Rebif® was approved in Europe in 1998 and is registered for use in more than 70 countries worldwide. By the end of 2001, Rebif® increased its leading position in these countries as the treatment of choice for patients with relapsing forms of MS with a market share of 38% in value terms and sales of \$379.6m outside the U.S.

Serono has studied Rebif® in approximately 3,000 patients and has over 7,000 patient-years of data on the therapy. This research demonstrates that there is an improved clinical response to higher doses and more frequent administration of interferon beta-1a in patients with relapsing remitting multiple sclerosis (RRMS).<sup>2,3</sup> Scientific research also supports Rebif®'s clinical premise that early treatment of RRMS with Rebif® 44 mcg (three times weekly, subcutaneously) decreases the frequency of clinical exacerbations and delays the accumulation of physical disability.

Rebif® is recommended for use at a dosage of 44 mcg three times per week injected subcutaneously.

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<sup>1</sup> EVIDENCE: Evidence for Interferon Dose-response European-North American Comparative Efficacy.

<sup>2</sup> The PRISMS (Prevention of Relapses and Disability by Interferon-(beta)-1a Subcutaneously in Multiple Sclerosis) Study Group and the University of British Columbia MS/MRI Analysis Group. PRISMS-4: Long-term efficacy of interferon-(beta)-1a in relapsing MS. *Neurology* 2001; 56: 1628-1636.

<sup>3</sup> Results of Comparative Efficacy Trial using two formulations of interferon beta-1a in RRMS. P. Coyle. 17<sup>th</sup> World Congress of Neurology Abs. Full data presented at a late breaker session, June 22 2001.

Most commonly reported side effects are injection site disorders, flu-like symptoms, abdominal pain, depression, elevation of liver enzymes and blood cell abnormalities. Rebif® is contraindicated in patients with hypersensitivity to natural or recombinant interferon, human albumin, or any other component of the formulation. Caution is advised in patients with depression, pre-existing seizure disorders, or liver problems. Women who are or are planning to become pregnant should not take Rebif® without consulting their doctor.

More information about Rebif® can be found in the full prescribing information, on line at [www.rebif.com](http://www.rebif.com) or by calling MS LifeLines at 1-877-44REBIF. Patients should be instructed to read the Medication Guide accompanying the product.

This agreement with Pfizer will be discussed by Serono management during the conference call due to be held on Wednesday July 24<sup>th</sup> on the occasion of Serono's 2<sup>nd</sup> quarter results.

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*Some of the statements in this press release are forward looking. Such statements are inherently subject to known and unknown risks, uncertainties and other factors that may cause actual results, performance or achievements of Serono S.A. and affiliates to be materially different from those expected or anticipated in the forward-looking statements. Forward-looking statements are based on Serono's current expectations and assumptions, which may be affected by a number of factors, including those discussed in this press release and more fully described in Serono's Annual Report on Form 20-F filed with the U.S. Securities and Exchange Commission on May 21 2002. These factors include any failure or delay in Serono's ability to develop new products, any failure to receive anticipated regulatory approvals, any problems in commercializing current products as a result of competition or other factors, our ability to obtain reimbursement coverage for our products, and government regulations limiting our ability to sell our products. Serono has no responsibility to update the forward-looking statements contained in this press release to reflect events or circumstances occurring after the date of this press release.*

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#### **About Serono**

Serono, Inc., located in Rockland, MA, is the US affiliate of Serono, S.A., a global biotechnology leader, headquartered in Geneva, Switzerland. The Company has six recombinant products on the market, Gonal-F® (follitropin alfa for injection), Luveris® (lutropin alfa), Ovidrel®/Ovitrelle® (choriogonadotropin alfa for injection), Rebif® (interferon beta-1a), Serostim® [somatropin (rDNA origin) for injection] and Saizen® [somatropin (rDNA origin) for injection]. (Luveris® is not approved in the USA).<sup>4</sup> In addition to being the world leader in reproductive health, Serono has strong market positions in neurology, metabolism and growth. The Company's research programs are focused on growing these businesses and on establishing new therapeutic areas. Currently, there are fifteen new molecules in development.

In 2001, Serono achieved worldwide revenues of US\$1.38 billion, and a net income of US\$317 million, making it the third largest biotech company in the world based on revenues. The Company operates in 45 countries, and its products are sold in over 100 countries. Bearer shares of Serono S.A., the holding company, are traded on the virt-x (SEO) and its American Depositary Shares are traded on the New York Stock Exchange (SRA).

#### **About Pfizer**

Pfizer Inc discovers, develops, manufactures and markets leading prescription medicines for humans and animals and many of the world's best-known consumer brands.

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<sup>4</sup> Package inserts for the company's US products are available at [www.seronousa.com](http://www.seronousa.com) or by calling 1-888-275-7376.

For more information, please contact:

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## SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

SERONO S.A.  
a Swiss corporation  
(Registrant)

July 11 2002  
\_\_\_\_\_, \_\_\_\_

By:   
Name: Jacques Theurillat  
Title: Deputy Chief Executive Officer and  
Chief Financial Officer